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Intra-operative Cone Beam Computed Tomography can Help Avoid Reinterventions and Reduce CT Follow up after Infrarenal EVAR

P. Törnqvist [*], N. Dias, B. Sonesson, T. Kristmundsson, T. Resch

Vascular Center, Department of Hematology and Vascular Diseases, Skåne University Hospital Malmö, Malmö, Sweden

WHAT THIS PAPER ADDS

This paper highlights the intra-operative effects of cone beam computed tomography (CT) by improving the technical outcome of endovascular aneurysm repair (EVAR), and also questions the need of routine early CT angiography after EVAR.

Objective/Background: Re-interventions after endovascular abdominal aortic aneurysm repair (EVAR) are common and therefore a strict imaging follow up protocol is required. The purpose of this study was to evaluate whether cone beam computed tomography (CBCT) can detect intra-operative complications and to compare this with angiography and the 1 month CT follow up (computed tomography angiography [CTA]).

Methods: Fifty-one patients (44 men) were enrolled in a prospective trial. Patients underwent completion angiography and CBCT during infrarenal EVAR. Contrast was used except when pre-operative renal insufficiency was present or if the maximum contrast dose threshold was reached. CBCT reconstruction included the top of the stent graft to the iliac bifurcation. Endoleaks, kinks, or compressions were recorded.

Results: CBCT was technically successful in all patients. Twelve endoleaks were detected on completion digital subtraction angiography (CA). CBCT detected 4/5 type 1 endoleaks, but only one type 2 endoleak. CTA identified eight type 2 endoleaks and one residual type I endoleak. Two cases of stent compression were seen on CA. CBCT revealed five stent compressions and one kink, which resulted in four intra-operative adjunctive manoeuvres. CTA identified all cases of kinks or compressions that were left untreated. Two of them were corrected later. No additional kinks/compressions were found on CTA. Groin closure consisted of 78 fascia sutures, nine cut downs, and 11 percutaneous sutures. Seven femoral artery pseudoaneurysms (<1 cm) were detected on CTA, but no intervention was needed.

Conclusion: CA is better than CBCT in detecting and categorizing endoleaks but CBCT (with or without contrast) is better than CA for detection of kinks or stentgraft compression. CTA plus CBCT identified all significant complications noted on the 1 month follow up CTA. The use of intra-operative CA and CBCT could replace early CTA after standard EVAR thus reducing overall radiation and contrast use. Technical development might further improve the resolution and usefulness of CBCT.

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INTRODUCTION

Endovascular repair of abdominal aortic aneurysm (EVAR) is the primary treatment option in anatomically suitable patients. Previous reports of EVAR have demonstrated a significant risk of secondary interventions for endoleaks, migrations, and stent graft failure, including aneurysm rupture. This has prompted the need for extensive post-operative follow up (FU). The gold standard for FU is contrast enhanced computed tomography angiography (CTA). However, this method exposes the patients to radiation, as well as contrast, which might lead to radiation induced malignancy and contrast induced renal nephropathy, respectively.[1,2] Ultrasound FU has therefore been used increasingly, but is limited in detecting structural problems with an endograft, such as kinks, migrations, and fractures.[3] Combined programmes with an early CTA and subsequent ultrasound have also been proposed, as an uneventful CTA is associated with improved late outcomes.[4] The development of intra-operative cross sectional imaging techniques such as cone beam computed tomography (CBCT) have been shown to be feasible both in EVAR planning and as completion imaging to detect complications missed by conventional angiography.[5,6]

The aim of this study was to evaluate the efficacy of completion CBCT in detecting intra-operative complications compared with standard final angiography. In addition,

* Corresponding author.
E-mail address: tornqvist.pelle@gmail.com (P. Törnqvist).

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completion CBCT was compared with the 1 month CTA to evaluate the use of CBCT alone as the primary modality for early post-operative imaging.

METHODS

The Regional Ethical Committee at Lund University approved the study and all patients gave written informed consent prior to enrolment. Fifty-one patients undergoing standard infrarenal EVAR were enrolled prospectively between October 2012 and December 2013. Two patients were excluded from analysis because of incomplete FU. Mean age was 72 years (range 57—91 years) and 43 were men. Patient mean body mass index was 26.8 (range 19.5—44.7). Stent grafts included the Zenith Flex (Cook Medical Inc., Bloomington, IN, USA; $n = 42$), Endurant (Medtronic Inc., Minneapolis, MN, USA; $n = 3$), Zenith LP (Cook Medical; $n = 2$) and Trivascular Ovation (Trivascular Inc., Santa Rosa, CA, USA; $n = 2$). All procedures were performed in an operating room equipped with a fixed ceiling mounted imaging system (Siemens Artis Zee; Siemens, Munich, Germany). After EVAR placement and balloon moulding of the stent graft, completion digital subtraction angiography (CA) was performed using a standard institutional protocol. A pigtail catheter was placed at the level of the renal arteries and 20 mL contrast injected in an antero-posterior projection at 20 mL/second using a power injector.

CBCT (DynaCT; Siemens) was performed intra-operatively after CA but before groin closure. CBCT included contrast enhancement, except in the presence of renal insufficiency or if the maximum contrast dose threshold was reached according to the OmniVis software (GE Healthcare) based on patients' glomerular filtration rate (GFR). CBCT was performed using Visipaque (GE Healthcare, Little Chalfont, UK) 140 mg/mL (9 mL/second for a total dose of 72 mL). CA and CBCT were both performed with apnoea.

The positioning of the detector (40 × 30 cm) was initially in horizontal mode during an 8 second rotation of 200 degrees, 0.5 degrees angular increment. With this setup, the entire stentgraft could often not be included, and the operator had to determine the area of greatest interest proximally or distally, to be included in the CBCT. This issue has been described earlier and has been a major limitation of the technique.[7,8] A software upgrade during the trial enabled a vertical (portrait) mode, which is superior in studying the stent graft. The detector is simply rotated 90 degrees thus allowing capture of a greater cranio-caudal segment (30 × 40 cm). The remaining CBCT protocol remained unchanged. Before a CBCT run, all guide wires were exchanged for catheters to reduce image artifacts (scatter).

The operator assessed the CA and the CBCT only after both had been completed. Imaging after processing with multiplanar reconstructions, maximum intensity projection, and three dimensions were performed at the operator's discretion using Inspace software (Siemens). Intra-operative adjunctive procedures to solve any additional findings noted on CBCT or CA were done at the discretion of the operator. The result was reviewed with the same modality that had demonstrated the finding (additional CBCT or DSA).

All patients underwent three phase CTA 4—6 weeks post-operatively according to a standard protocol. The FU CTA protocol was performed with a Somatom Sensation 16 Scanner (Siemens) using Omnipaque 350 mg/mL, 120 mL during a 15 second injection. The scanning was performed in three phases. One pre-contrast scan was followed by an arterial phase scan. Finally, the late venous phase was performed after an 80 second delay. The area of interest was between xiphisternum and lesser trochanter. CTAs were evaluated by the EVAR operator and were compared with the intra-operative CBCT findings.

The main purpose was to evaluate the peri-operative complications identified by CBCT in relation to CA and to determine whether the 1 month CTA identified additional complications.

Anatomical details

All cases were measured by center line calculations using the Aquarius iNuition program (Terarecon Inc., Foster City, CA, USA). Abdominal aortic aneurysm (AAA) diameters were measured by the same observer using the shortest transverse diameter at the widest point of the aneurysm sac and at the proximal neck of abdominal aorta. The mean aneurysm diameter was 56.2 × 61.0 mm (range 21.0—10.0 mm). The aortic neck diameter at the lowest renal artery was a mean of 22.3 × 23.3 mm (range 17.0—30.0 mm). The mean aortic diameter 15 mm below the lowest artery was 24.3 × 25.6 mm (range 18—43 mm). 39.2% of stent grafts met the instructions for use criteria provided by the manufacturer.

Statistics

Results are given as mean (range). All calculations were performed using SPSS Statistics version 22 (IBM, Armonk, NY, USA). The Mann—Whitney *U* test was used to measure the difference in creatinine levels. $p < .05$ was considered statistically significant.

RESULTS

The mean operating time was 142 (66—308) minutes. The mean total radiation dose was 2,0433.4 (4934.5—59,366.9) μGym^2. The mean total radiation dose for CBCT was 7064.8 (3490.9—12,645.4) μGym^2. The mean total contrast dose was 28.1 (0—49.0) g iodine, including 8.9 g for CBCT (fixed injection). Owing to renal insufficiency, one patient did not receive any contrast, and the operation was completed with CO_2 imaging. All procedures were initiated percutaneously and groin closure included 35 bilateral fascia sutures, seven unilateral open femoral artery closures (planned) combined with contralateral fascia suture, and five cases of bilateral Perclose (Abbot Inc., Chicago, IL, USA). One patient received unilateral percutaneous closure and a contralateral fascia suture.

Intra-operative findings found on CA, CBCT, and FU CTA are shown in Table 1 and further described below.

Table 1. Summary of findings present on completion angiography (CA), cone beam computed angiography (CBCT) and follow up computed tomography angiography (FU CTA).

	CA	CBCT	FU CTA
Type 1 endoleak	5	4	1
Type 2 endoleak	7	1	8
Stent graft compression	2	5	1
Stent graft kink	0	1	1
Interventions	10		3

Note. No type 3 or 4 endoleaks were found. Only three of the type 2 endoleaks present on CA were also present on the FU CTA.

CA: intra-operative findings

CA identified 12 endoleaks (type 1a, $n = 5$; type 2, $n = 7$). Two type 1a endoleaks were treated during the primary operation. One type 1a endoleak was intentionally left untreated, as it required a later proximal extension with a fenestrated cuff (Fig. 1). Two additional type 1a endoleaks were left untreated at the surgeon's discretion after repeated percutaneous angioplasty as they were small and noted during full heparinization (activated clotting time $>$ 300 seconds). Both had resolved on 1 month FU CTA. No type 3 or 4 endoleaks were found. Two cases of stent graft compression were noted, but no significant kinks were found on the completion angiogram.

CBCT: intra-operative findings

CBCT identified 4/5 type 1a endoleaks present on CA, but only one type 2 endoleak (Fig. 2). The type 1a endoleak that was missed by CBCT was minimal on CA and was no longer present at FU CTA. Contrast enhanced CBCT was used in all patients with type 1a endoleak present on CA. Nine of the 12 patients with endoleak on CA had a contrast enhanced CBCT, while the remaining three were plain CBCT.

Five cases of endograft compression and one kink were identified by CBCT. These findings resulted in four adjunctive procedures to correct the SG compression in addition to the correction of the two type 1a endoleaks also seen on CA.

FU CTA

CTA identified nine endoleaks (one type 1a, eight type 2). Four of these were seen intra-operatively (one type 1a, three type 2). One patient had a persistent type I endoleak, which was intentionally left untreated at the primary surgery, as described above. The other endoleaks were type 2 and had been identified by intra-operative CA. One case of kinking and one case of stent graft compression were seen. All structural findings of the stent graft on FU CTA were also seen on the primary CBCT, but were left untreated at the surgeon's discretion during the primary operation. Seven small pseudoaneurysms ($<$1 cm) after fascia closure ($n = 78$) were found but none warranted repair.[9] Two cases of aneurysm growth between the pre-operative CTA and the post-operative CTA were found. In one of these cases the expansion was combined with a type 2 endoleak at 1 month. An additional 6 month CTA showed decreasing aneurysm diameter and resolution of the type 2 endoleak. When comparing the pre-operative CTA and the FU CTA, another case showed significant sac expansion. However, there was $>$6 months between these two investigations.

Re-interventions

Three re-interventions were performed based on FU CTA. Other than the known type 1a endoleak these were due stent graft kink and stent graft compression, which had also been present and noted on the intra-operative CBCT but which were considered at the time, to be non-significant by the operator, as stated above.

Renal function

Creatinine was measured pre-operatively and at the time of the FU CTA. Data were available in 47/49 patients. Pre-operatively creatinine was 91.6 (59–189) µmol/L and post-operatively 94.4 (52–239) µmol/L (p = .595). Four patients had an increase $>$25% in creatinine level 1 month post-operatively.[10] Two of these had $>$50% elevation. Owing to partial stent graft coverage of the renal artery

Figure 1. This figure shows the type 1 endoleak present during the implantation of an infrarenal stentgraft. (A) Pre-contrast cone beam computed tomography (CBCT) compared with (B) the contrast enhanced CBCT displaying a type 1 endoleak (arrow). (C) Completion angiography also reveals the proximal type 1 endoleak. (D) Follow up CT verifies the type 1 endoleak (arrow), which was left intentionally because of the need for a fenestrated cuff.

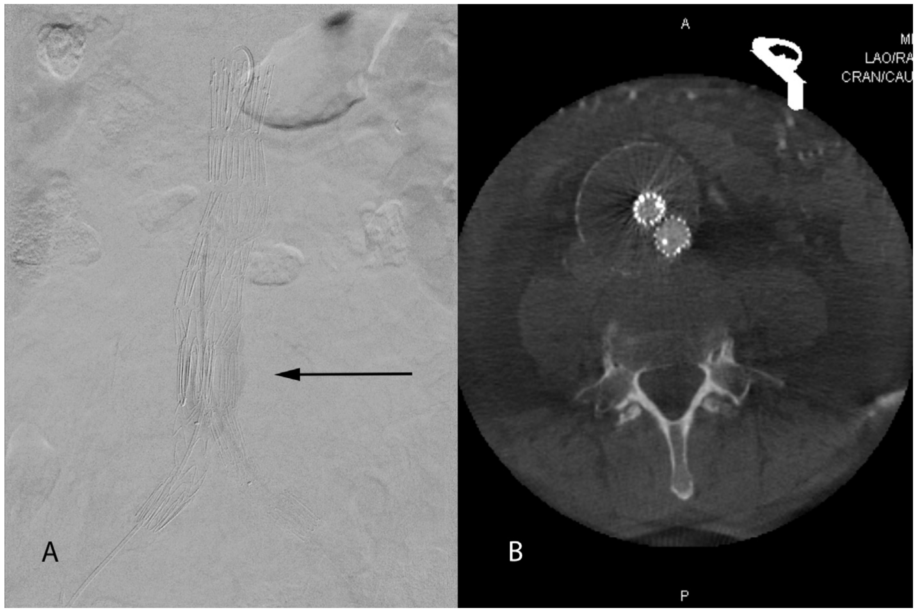

Figure 2. (A) Type 2 endoleak on the completion angiogram (arrow). (B) Contrast enhanced cone beam computed tomography did not show the type 2 endoleak.

ostium, one patient underwent renal stenting on post-operative day 1. During the intervention a dissection of the renal artery occurred resulting in partial loss of renal parenchyma thus explaining the reduction in renal function. The other patient had an accessory renal artery covered by the stent graft.

DISCUSSION

One of the main disadvantages of EVAR compared with open repair is the increased frequency of secondary interventions, which necessitates routine FU imaging. Many of the re-interventions are required early after EVAR, which might be a reflection of the inability to detect and consequently treat the complications intra-operatively. Conventional angiography evaluates the operative result with a two dimensional approach. Thus, for complete evaluation, multiple projections are required. This is time consuming and increases contrast use significantly. The use of intra-operative three dimensional (3D) imaging techniques such as CBCT might overcome some of the limitations of CA. CBCT has the potential to reduce both the need for early secondary interventions and perhaps also the need for routine early CTA FU.

In the present study, stent graft compressions and kinks were found more often with CBCT than with CA alone and could thus be treated before groin closure. Indeed, the compressions/kinks that were found on the FU CTA were also present on the intra-operative CBCT (Fig. 3). Thus, the FU CTA did not add any information on stent graft configuration failures. In one case, the information from the CBCT and CA revealed a partially covered renal artery, which was initially left at the surgeon's discretion. When presented for review, the decision was made to re-intervene based on the information given from the intra-operative 3D imaging.

In this study, CA was more efficient than CBCT in endoleak detection. However, the majority of endoleaks detected on CA and not on CBCT were type 2 and warranted no further treatment in the operative setting. Of the 12 endoleaks that were found on CA, contrast CBCT was used in nine of them; therefore, the detection rate is not entirely comparable. Four of five type 1a endoleaks detected on CA were found by CBCT, but the impression was that they were not as clearly outlined on CBCT as on CA. The type 1a endoleak that CBCT missed was left untreated and resolved spontaneously. One explanation for this might be that a low contrast concentration was used for the CBCT to minimize the contrast load for the patient. With future enhancement to intra-operative image resolution this might become less of an issue.

Extensive surveillance programmes after EVAR have been developed as the re-intervention rate after EVAR is around 20% after 4 years.[11] The main objective of a FU CTA is the detection of endoleaks, migration, kinking, and thrombosis of the stent graft. However, previous publications have shown that complications that warrant re-intervention most often present outside the surveillance programme,[12] and thus the relevance of intense CTA FU remains questionable. Other studies have also shown that an early uneventful CTA may allow a FU free interval of 3—5 years.[4,13] This study shows that the combined used of plain CBCT and CA provides the same clinical relevant information as the 1 month CTA. This suggests that the 1 month CTA may be unnecessary in some patients. Moreover, other modalities including ultrasound give enough information about the stent graft dynamics and whether any aneurysm growth is present to continue avoiding CTA in the FU of EVAR.[14]

The highest rate of complications and re-interventions after EVAR are often noted within the first 30 post-operative days,[15] with early re-interventions being

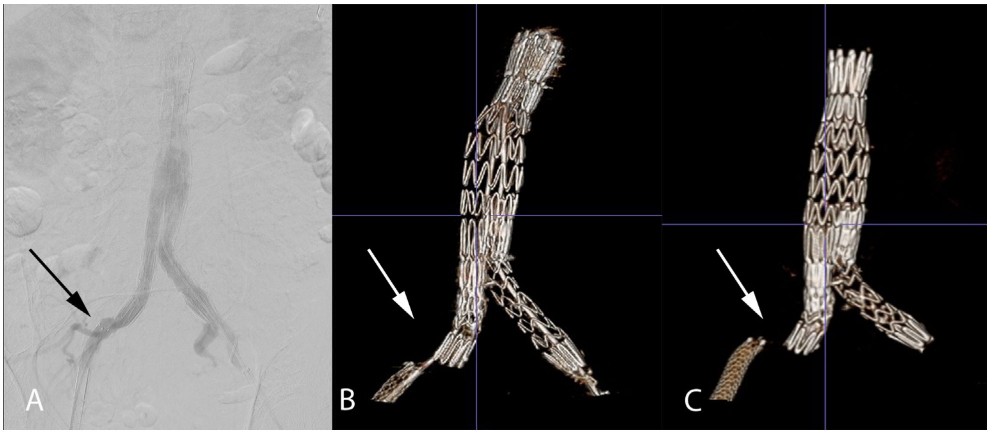

Figure 3. Mis-alignment between the stents in the right iliac. (A) Completion angiography. The black arrow displays the area of interest. (B) Cone beam computed angiography (CBCT). The white arrow clearly shows kink between the iliac limb and the native artery. (C) Follow up computed tomography angiography (FU CTA) displays the same finding as the intra-operative CBCT. Note the effect of the absent guidewire when comparing CBCT and FU CTA.

performed in 10%.[16] Some advocate three projection imaging as not all stent graft kinks or compressions are easily seen on CA alone.[17] In this study, the 1 month re-intervention rate following the FU CTA was 6%, the majority due to kinks or compressions. However, all stent graft structural findings found on the FU CTA were also present on the CBCT. Compared with the literature, the early re-intervention rate in the current series is lower than expected. This was most likely significantly influenced by the use of CBCT for the detection and correction of structural stent graft problems intra-operatively.

Biasi et al. have previously described the utility of CBCT in a retrospective series.[7] The results of the study by Biasi et al. showed that early complications were due to technical failures in up to 86% of cases and supposedly corrected with better intra-operative imaging.[7] The use of CBCT resulted in adjunctive procedures in 6.25% of the patients in the study by Biasi et al.,[7] while in the present study 8.1% of the patients had benefited from the CBCT intra-operatively. Abbruzzese et al. reported adjunctive procedures in 25% of patients of whom approximately 14% were technical failures and the other procedures were to treat endoleaks.[18]

In the present series there was a tendency towards higher creatinine levels post-operatively; however, this was not statistically significant. Owing to severe renal impairment, only one patient had the operation performed with CO_2 as the contrast agent. Biasi et al. reported the use of CO_2 in up to 40% of the cases, perhaps as they were constrained owing to the high contrast dose in the CBCT protocol.[7] In the present study, only 60% of the amount of iodine reported by Biasi et al.,[7] and 70% of that reported by Eide was used.[8] Despite this, 4/5 type 1a endoleaks were detected in the ‘low-dose’ CBCT in the present study. Further investigations are needed to generate the ideal CBCT protocol for detecting endoleaks. Timing, and the amount and concentration of iodine contrast during CBCT might play a significant role in detecting endoleaks. CA is perhaps better for diagnosing type 2 endoleaks as they tend to become evident late in the angiographic run. However, the relevance of intra-operative type 2 endoleak detection is questionable, as the majority will disappear in early FU, and treatment is ultimately reserved for those with an increasing AAA diameter during FU.

Another issue is the radiation dose for CBCT. The CBCT radiation dose used in this study was half that used in the studies by Biasi et al. and Eide et al. (3,574.0 μGym^2 vs. 7,064.8 μGym^2).[7,8] The total procedure radiation dose was 38% higher in the present study than that of the study by Biasi et al.,[7] but was 21% less than that in the report by Eide et al.[8]

There are several explanations for this. Firstly, Biasi et al. and Eide et al. used the horizontal view of the flat panel in the CBCT protocol,[7,8] while in the present study a vertical view mode was used. The portrait mode scans a larger volume of tissue than the horizontal mode, where a greater portion of the scan includes an area outside of the patient. Secondly, a 9 second programme rendering 397 projections was used versus 248 in the studies of Biasi et al. and Eide et al.,[7,8] which were based on a 5 second programme. There is a commercially available Siemens CBCT protocol utilizing a 5 second portrait mode, giving lower radiation. This might give sufficient information, but has not yet been investigated. However, the radiation dose in CBCT must be seen in relation to the benefits it provides. Failure to detect an intra-operative complication and then subjecting the patient to radiation exposure during FU CTA and possible later re-interventions might lead to an overall greater radiation exposure. These considerations were outside of the realms of the present study and warrant further investigation.

There are some limitations of the current study. The CBCT and CA evaluations were done by the operators without a definitive definition of what constituted a significant kink, compression, or endoleak, and any finding was based on clinical judgement. In addition, the true clinical relevance of a positive finding on CA or CBCT that led to an additional procedure is ultimately unknown, as they were treated on detection. These issues might have been better evaluated in a randomized trial. However, as CBCT was already used in clinical practice when the study started, this was difficult to implement. The number of patients included made the study underpowered to calculate the sensitivity and specificity for CBCT to detect subgroups of endoleaks. Further studies are needed to evaluate this.

CONCLUSION

This study indicates that intra-operative technical problems such as kinks and stent graft compression are better detected with CBCT than with conventional angiography. This provides the possibility of intra-operative correction, thus removing the need for secondary interventions. Clinically relevant endoleaks are equally well seen on contrast enhanced CBCT and CA. Early FU CTA did not add additional information about the stent graft configuration. Endoleaks found on early CTA FU but not seen on CBCT or CA were all type 2 and did not lead to further intervention. The present results question the relevance of routine early CTA if CBCT is used. Further studies should be performed to determine whether CBCT combined with CA as the final check can replace early FU CTA, and thereby reduce overall contrast and radiation exposure in the peri-operative setting.

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CONFLICT OF INTEREST

None.

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